[10121/0090]

3737

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Roy SULLIVAN
Serial No.	:	09/603,886
Filed	:	June 26, 2000
For	:	APPARATUS AND METHOD FOR PERFORMING A TISSUE RESECTION PROCEDURE
Group Art Unit	:	3737
Examiner	:	Runa S. Qaderi

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By: Oleg F. Kaplun (Reg. No. 45,559)
Date: April 19, 2004

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S I R:

Transmitted herewith please find three (3) copies of an Appeal Brief for filing in the above-identified application.

The Commissioner is hereby authorized to charge the Appeal Brief filing fee of $330 and a one-month extension fee of $110 and any additional fees required to the Deposit Account of **Fay Kaplun & Marcin, LLP No. 50-1492**. A copy of this Transmittal is enclosed for that purpose.

Respectfully submitted,

Dated: April 19, 2004

By: _____
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APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Sir:

In support of the Notice of Appeal filed December 29, 2003, and pursuant to 37 C.F.R. § 1.192, appellee presents in triplicate their appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 33-42 in the final Office Action dated June 4, 2003 as clarified in the Advisory Action mailed December 10, 2003. The appealed claims are set forth in the attached Appendix A.

1. Real Party in Interest

This application is assigned to SciMed Life Systems Inc., the real party in interest, by an assignment recorded at Reel 011406, Frame 0852 on December 21, 2000.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 33-42 are pending.

Claims 33-42 have been rejected in the final Office Action and are involved in this appeal.

4. Status of Amendments

All amendments filed by the appellee have been entered. None were submitted after the Advisory Action.

5. Summary of the Invention

The invention is directed to an apparatus and method for performing a tissue resection procedure on target tissue within a body lumen. Specifically, the present invention is directed to an endoluminal procedure which provides for identifying target tissue margins and guiding a tissue resection device to the target tissue. The endoluminal procedures may take place in vascular, gastrointestinal, or air exchange lumens, and may involve disease diagnosis and/or treatment. A procedure that is often carried out endoluminally is the removal of "suspect" or diseased tissue in order to provide tissue samples for histological analysis or removal of diseased tissue as a treatment means.

In a more specific example shown in Figures 1 and 2, the present invention

utilizes an endoluminal device 100 to harvest diseased tissue from within a body lumen. *Specification*, page 2, lines 4-5. The device 100 comprises a flexible catheter body 110 with a proximal end 112 and a distal end 114. The proximal end of the device 100 contains various control mechanisms such as a suction adjust knob 120 and a head-actuating handle 150. At the distal end 112 there is a head assembly 180 and a tissue-harvesting chamber 190. *Specification*, page 2, lines 6-20.

Figure 2 illustrates the distal end 114 of the device 100 as it is inserted into a body lumen to resect tissue 200 and remove suspect tissue 210. The suction at the distal end 114 is adjusted using the suction adjust knob 120 to draw the tissue 200 into the tissue-harvesting chamber 190. *Specification*, page 3, lines 4-10. Once the tissue 200 is in a desired position, the head assembly 180 is retracted to perform the resection. The suspect tissue 210 is removed and the site is stapled using staples contained in the head assembly 180. With the tissue sample 210 enclosed within the tissue-harvesting chamber 190, the device 100 is removed from the body lumen. *Specification*, page 3, lines 11-15.

The specification describes a positioning system 300 for guiding the device 100 to a tubular organ 410 within a body wall 400 of a patient and controlling resection of a desired portion of tissue of the tubular organ 510 including a lesion 420. The positioning system 300 includes a fluoroscope 310, an x-ray imaging sensor 320, video processing electronics 330, a computer 340, a video display 350, and an alarm device 360. *Specification*, page 4, lines 19-30.

The fluoroscope 310 passes x-rays through the patient and the lesion 420. A radiopaque dye, selectively absorbed by the lesion 420 is applied to create an image of boundaries of the lesion 420 as the x-rays are collected by the x-ray imaging sensor 320.

Specification, page 4, lines 31-33. Image data from the x-ray imaging sensor 320 is then communicated to the video processing electronics 330, which process the image data and provides the data to the computer 340. The processed image data is further analyzed by the computer 340 to identify and to display a predetermined tissue margin 420A as well as the position of the device 100 inside the tubular organ 410 on the video display 350. *Specification*, page 5, lines 2-10. The alarm 360 alerts the operating physician if the device 100 is not properly aligned for resectioning the lesion 420 (i.e., outside the tissue margin 420A). Thus, the alarm 360 prevents severing too much or too little of the tissue surrounding the lesion 420. *Specification*, page 5, lines 11-16.

The computer 340 may also serve additional roles. For instance, it may be connected to other components of the positioning system 300 to provide for centralized control. The computer 340 may be directly connected to the device 100 and thus control the resectioning procedure. In this embodiment, the alarm 360 would alert the computer 340 directly as a precautionary measure, so that the computer 340 may, for example, disable the device 100. *Specification*, page 9, lines 5-26. In another embodiment, the computer 340 may be coupled to the fluoroscope 310 to obtain better quality image data. *Specification*, page 5, lines 27-31.

6. Issues

I. Whether the specification fails to provide proper antecedent basis for claimed subject matter under 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o).

II. Whether claims 33-37 and 40-42 recite patentable subject matter under 35 U.S.C. § 103(a) over U.S. Patent No. 6,214,018 to *Kreizman et al.* in view of U.S. Patent No.

4,796,673 to *Mascuch et al.* and U.S. Patent No. 5,868,760 to *McGuckin, Jr.*

II. Whether claims 38 and 39 recite patentable subject matter under 35 U.S.C. § 103(a) over U.S. Patent No. 6,214,018 to *Kreizman et al.* in view of U.S. Patent No. 4,796,673 to *Mascuch et al.* and U.S. Patent No. 5,868,760 to *McGuckin, Jr.*, and in further view of U.S. Patent No. 5,485,839 to *Aida et al.*

7. Grouping of Claims

Claims 33-42 stand together.

8. Argument

I. The Objection to the Specification for Failure to Provide Proper Antecedent Basis for Claimed Subject Matter Should be Reversed

In the final Office Action and the Advisory Action the Examiner asserted that the specification fails to provide proper antecedent basis for claimed subject matter and must be corrected to include terms "flexible body" and "a naturally occurring body orifice." Appellee disagrees with the objection under 37 C.F.R. 1.75(d)(1). For at least the following reasons, the Board should reverse the objection.

The Specification contains clear support and antecedent basis for the terms "flexible body" and "naturally occurring body orifice" appearing in the claims. In response to the first Office Action dated February 19, 2003, the appellee canceled claims 1-32 and added new claims 33-42 as set forth in the attached Appendix A. In the final Office Action dated June 4, 2003, the Examiner rejected claims 33-42 under 35 U.S.C. § 112, first paragraph, as failing to

comply with the written description requirement as claim 33 recited a "flexible body" and "a naturally occurring body orifice," which terms were not included in the original disclosure. In the response to the final Office Action filed September 4, 2003, the appellee amended the specification to incorporate subject matter from a patent which was incorporated by reference, adding a paragraph describing the structure corresponding to those terms. With respect to "flexible body," the appellee stated that, "the present invention may be utilized with a flexible endoscopic resection system including a *flexible endoscope*." In addition, in the original specification, the appellee described the endoluminal device as having "a flexible catheter body 110."

These term descriptions clearly comply with the requirements of 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o). 37 C.F.R. 1.75(d)(1) states that, "the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." Furthermore, MPEP § 608.01(o) also states:

> While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by an amendment of the claims so as to have clear support or antecedent basis in the specification fo the new terms appearing in the claims.

The above-cited sections merely require that each term appearing in the claims must have a meaning which can be readily ascertained by reference to the specification and not that the exact same terms must be used in the specification as well as in the claims. In appellee's application, the terms used in the specification, "a flexible catheter body 110" and "a flexible endoscope,"

provide clear and unequivocal support for the term "flexible body" recited in claim 33. Therefore, the term "flexible body" as recited in claim 33 is supported by the specification as required under 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o).

The Examiner has also objected to the term "a naturally occurring body orifice" as recited in claim 33. In the amended portion of the specification, the appellee stated that the "endoscope is inserted into *a body orifice* to locate a lesion, for example, in *a tubular organ* under visual observation (usually insufflating the organ)." It is respectfully submitted that those skilled in the art will understand that the description in the specification of a body orifice refers specifically to a naturally occurring body orifice and that this description provides clear antecedent basis for the claim term "naturally occurring body orifice" as recited in claim 33. Thus, it is respectfully submitted that the terms used in the specification provide clear support for the terms "flexible body" and "naturally occurring body orifice" as recited in claim 33, and that this claim fully complies with 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o).

Therefore, appellee respectfully requests that the Board overturn the Examiner's objection to the specification Under 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o).

II. The Rejection of Claims 33-37 and 40-42 Under 35 U.S.C. § 103(a) as Unpatentable Over *Kreizman et al.* in view of *Mascuch et al.* and *McGuckin, Jr.* Should Be Reversed

In the final Office Action the Examiner asserted that *Kreizman et al.* describes an apparatus and method for removing tissue from a body part using a resection device, an imager, an image processing unit, and a control unit. *Final Office Action*, page 3, ¶ 4. The Examiner admitted that *Kreizman et al.* fails to disclose a surgical method and apparatus for resecting tissue

and using radiopaque dye to mark the lesion. The Examiner thus concluded that *McGuckin, Jr.* teaches a resectioning device and *Mascuch et al.* discloses the use of radiopaque dye in surgical procedures. *Final Office Action*, page 4, ¶ 4- page 5, ¶ 2. Appellee disagrees with the rejection of claims 32-37 and 40-42 under 35 U.S.C. § 103(a). For at least the following reasons, the Board should reverse the rejection.

Kreizman et al. does not show or suggest a system for the location and identification of tissue to be resected with a flexible resection device, as recited in claim 33. The Examiner asserted in the final Office Action that *Kreizman et al.* describes a method and apparatus 10 "for removing a tissue from a volume surrounding a region of interest within the body part of a patient". *Id.* at col. 2, lines 5-8. The apparatus 10 includes a stereotactic imaging assembly having a radiation transmission source 16 and a radiation receiver 18, a body part holder 12, a display 24, a user interface 26, a motorized tissue removal tool guiding stage 28, and a controller 36. *Id.* at col. 3, line 47 -col. 4, line 23.

The method 100 disclosed in *Kreizman et al.* includes the step of "holding a body part of a patient having a region of interest therein relative to a predetermined point of reference." *Kreizman et al.* at col. 2, lines 49-51. More specifically, the first step of method 100 is to hold a body part of a patient having a region of interest therein to establish a point of reference for the apparatus. *Kreizman et al.* at col. 6, lines 22-25. This step is accomplished using the body part holder 12 which is "adapted to hold a body part 14, such as a breast, immobile and to define a predetermined point of reference." *Kreizman et al.* at col. 3, lines 50-52. The holder 12 is described as including a movable compression paddle 44 and a movable compression plate 46 which define a predetermined point of reference about the breast 14 and

which hold the breast immobile and compressed. *Kreizman et al.* at col. 5, lines 23-27. The holder 12 also provides position indicating signals to the controller 36 which calculates "the size and location of a tissue removal volume relative to the predetermined point of reference." *Id.* at col. 4, lines 35-38.

The imaging assembly is also dependent on the immobilization of the body part 14 and is "adapted to obtain stereotactic images of the body part 14 held by holder 12 and the region of interest therein." *Kreizman et al.* at col. 3, lines 58-60. The stage 28 is used for guiding a removal tool 30, which is a rigid tissue removal instrument, such as a biopsy needle, a rotary cutting tool, or an ultrasonic surgical aspiration tissue removal tool. *Id.* at col. 5, lines 43-50. The stage 28 is also adapted to provide position indicating signals to indicate the position of the stage 28 relative to the predetermined point of reference defined by the holder 12. *Id.* at col. 4, lines 15-19. Based on the signals transmitted by the stage 28 and the holder 12, the controller 36 guides the stage and the removal tool 30 to the target site to remove the lesion. *Id.* at col. 4, lines 39-43.

Claim 33 recites a tissue resectioning system, comprising "a resection head mounted at a distal end of an elongate flexible body, the resection head including a marker thereon wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen from a naturally occurring body orifice" and "an imager which remains outside the patient's body, the imager generating image data of a selected region within the patient's body including a predetermined portion of tissue marked for resection" in combination with "an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker" and "a control unit

controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue."

As described above, *Kreizman et al.* shows a rigid device requiring a body part holder for holding a body part including a tissue to be removed immobile so that a point of reference may be defined relative to the immobilized body part. *Kreizman et al.* at col. 2, lines 4-8. Thus, this system is completely incompatible with the claimed system comprising "a resection head mounted on a distal end of an elongate flexible body" and operating within a body lumen where the region of tissue in question cannot be immobilized or located with respect to a point of reference defined by a rigid device. The apparatus and method of *Kreizman et al.* are suitable only for use with body parts which can be immobilized relative to an imaging apparatus. Conversely, the present invention locates and defines a volume of tissue for removal without using a predetermined point of reference. Instead, the present invention includes "an imager which remains outside the patient's body generating image data of a selected region within the patient's body including a predetermined portion of tissue marked for resection" and "an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker." This arrangement provides the necessary image data required in guiding a flexible body to the target site for resectioning.

In addition, the apparatus of *Kreizman et al.* only operates with a rigid removal tool that can be guided into a body part using the predetermined reference point . In contrast, the present invention uses "a resection head located within a body lumen with an elongate flexible body extending through the body lumen from a naturally occurring body orifice" to resect target tissue. Specifically, *Kreizman et al.* neither shows nor suggests any apparatus which would

allow such a volume of tissue in an internal organ to be located and defined so that a resection device could be controlled to remove the volume of tissue. Therefore, *Kreizman et al.* does not suggest a modification using a flexible resectioning device in place of the disclosed rigid tissue removal tool.

The cited references do not show or suggest, either taken alone or in combination, a system for the location and identification of tissue to be resected with a flexible resection device, as recited in claim 33. The Examiner admitted that neither *Kreizman et al.* or *Mascuch et al.* either showed or suggested a surgical method and apparatus for resecting tissue. *Final Office Action*, page 5, ¶ 2. To cure that defect, the Examiner cited *McGuckin, Jr.*, which teaches a method and apparatus for endoluminally resecting tissue. Although *McGuckin, Jr.* discloses an endoluminal resectioning device, it does not suggest the specific modification the Examiner contemplated. More specifically, *McGuckin, Jr.* fails to suggest substituting a flexible endoluminal resectioning device for the rigid removal tool of the system taught in *Kreizman et al.* nor does any of the cited references show or suggest any system capable of controlling such a flexible resection system as claimed.

Although *McGuckin, Jr.* states that the system is not limited to any particular type of a diagnostic imaging guidance," it provides no guidance on the implementation of guidance systems other than endoscopically assisted imaging. *Id.* at col. 3, lines 59-65. For instance, *McGuckin, Jr.* describes in detail various components of the resectioning apparatus required to provide providing visual guidance, such as an eyepiece 224, an input light source 226, and fiberoptics connectors that provide the physician with a view ahead of the resectioning device. *Id.* at col. 12, lines 16-46. However, *McGuckin, Jr.* includes no showing or suggestion of any

automatic control of a resection head based on any imaging data.

As the Federal Circuit has made clear, the prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991) and it is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991). More specifically, *it is improper to modify a prior art reference unless the prior art suggests the desirability of the specific modification*. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). In the case at hand, *McGuckin Jr.*, merely states that certain modifications of its apparatus are possible and only describes one specific image guidance system. Therefore, it is improper to modify *Kreizman et al*, since neither of the above-discussed references suggest such a modification.

Accordingly, for at least the reasons described above, the appellee respectfully submits that none of the cited references either shows or suggests a tissue resection system comprising: "a resection head located within a body lumen with an elongate flexible body extending through the body lumen from a naturally occurring body orifice" in combination with

"an imager which remains outside the patient's body generating image data of a selected region within the patient's body including a predetermined portion of tissue marked for resection and an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker" and "a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue," as recited in claim 33. Therefore, appellee respectfully requests that the Board overturn the Examiner's rejection of claim 33 under 35 U.S.C. § 103(a) as well as the rejection of claims 34-37 and 40-42 dependent therefrom.

III. The Rejection of Claims 38 and 39 Under 35 U.S.C. § 103(a) as Unpatentable Over *Kreizman et al.* in view of *Mascuch et al.* and *McGuckin, Jr.* and in further view of *Aida et al.* Should Be Reversed

In the Final Office Action, the Examiner asserted that *Kreizman et al.* describes an apparatus and method for removing tissue from a body part using a resection device, an image, an image processing unit, and a control unit. *Final Office Action*, page 3, ¶ 4. The Examiner admitted that *Kreizman et al.* fails to disclose a surgical method and apparatus for resecting tissue using radiopaque dye to mark a lesion and providing an alarm system in the controlling mechanism. The Examiner stated that *McGuckin, Jr.* teaches a resectioning device as claimed and that *Mascuch et al.* discloses the use of radiopaque dye in surgical procedures while *Aida et al.* teaches a medical treatment apparatus including alarm means. *Final Office Action*, page 4, ¶ 4- page 6, ¶ 1. Appellee respectfully disagrees with the rejection of claims 38 and 39 under 35 U.S.C. § 103(a) for at least the following reasons.

The rejection of claims 38 and 39 under 35 U.S.C. §103(a) should be reversed. Claims 38 and 39 depend from independent claim 33. As discussed above, *Kreizman et al.*, *Mascuch et al.*, and *McGuckin, Jr.*, either taken alone or in combination fail to show or suggest the system of claim 33. *Aida et al.* purports to show a tissue therapy system including an alarm means to notify an operating physician of a deviation from a predetermined treatment plan. However, *Aida et al.* is directed to a non-surgical device -- an ultrasonic device for the treatment of calculi. Thus, it is respectfully submitted that *Aida et al.* fails to cure the defects in the combination of *Kreizman et al., Mascuch et al.,* and *McGuckin, Jr.* Nor does *Aida et al.* provide any motivation for the suggested combination as it is directed to a non-surgical device. Therefore, at least for these reasons, it is respectfully submitted that claims 38 and 39 are also allowable. Appellee respectfully requests that the Board overturn the Examiner's rejection of these claims.

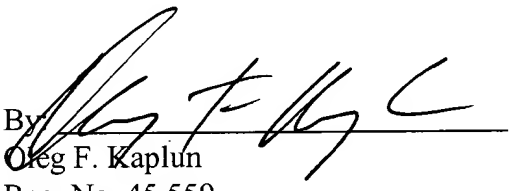
9. Conclusions

For the reasons set forth above, the appellee respectfully requests that the Board reverse the objection to the specification under 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o) and the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a), and indicate that claims 33-42 are allowable.

Respectfully submitted,

FAY, KAPLUN & MARCIN, L.L.P.

Date: April 19, 2004

By: 
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APPENDIX A – APPEALED CLAIMS

33. A tissue resectioning system, comprising:

a resection head mounted at a distal end of an elongate flexible body, the resection head including a marker thereon wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen to a naturally occurring body orifice;

an imager which remains outside the patient's body, the imager generating image data of a selected region within the patient's body including a predetermined portion of tissue marked for resection;

an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker; and

a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.

34. The system according to claim 33 wherein the imager includes a fluoroscope and an x-ray imaging sensor.

35. The system according to claim 33 wherein the marker is radiopaque.

36. The system according to claim 33 wherein the defined region of tissue and the location of the marker are displayed on a video display coupled with the control unit.

37. The system according to claim 33 wherein the control unit disables the resection head if the marker indicates that the resection head is oriented outside the defined region of tissue.

38. The system according to claim 33 further comprising an alarm device wherein the control unit transmits an alarm signal to the alarm device when the marker indicates that the resection head is oriented outside the defined region of tissue.

39. The system according to claim 38 wherein the alarm device generates a visual alarm on the video display.

40. The system according to claim 33 wherein the imager is a magnetic resonance imager.

41. The system according to claim 33 wherein the control unit determines the defined region of tissue by an absolute measure of tissue.

42. The system according to claim 33 wherein the control unit determines the defined region of tissue by a percentage of a physical dimension of the lesion.